June 10, 2019

Ards, Limited, RAC & CQE
George Hattub
Senior Staff Consultant
Medicsense, USA
291 Hillside Avenue
Somerset, Massachusetts 02726

Re: K071803
Trade/Device Name: ARDS Dental Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: August 12, 2008
Received: August 14, 2008

Dear George Hattub:

This letter corrects our substantially equivalent letter of September 05, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

for Srinivas Nandkumar, Ph.D.
Acting Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071803

Device Name: ARDS Dental Implants

Indications For Use: ARDS dental implants are indicated for use in surgical and restorative applications for placement in the bone of the upper and lower jaw to provide support for prosthetic devices in order to restore the patient's chewing function. ARDS dental implants are indicated for two-stage surgery.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K071803

510(k) Summary of Safety & Effectiveness

K071803

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

1. (a)	**Submitter Address:**	George J. Hattub MedicSense, USA 291 Hillside Avenue Somerset, MA 02726 www.medicsense.com

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1. (b)	***Manufacturer Address:***	ARDS, Ltd. 4 Hasikma St. Rishon Lezion, Israel 75201
	Mfg. Phone:	972-3-969-0954
	Contact Person:	Dr. Uri Arny, CEO
	Date:	March 7, 2008
2.	***Device & Classification Name:***	Endosseous Dental Implant, Class 2, Product Code DZE, 21 CFR 872.3640 ARDS Dental Implants
3.	***Predicate Device:***	Alpha Bio Dental Implant System (K063364)
4.	***Description:***	ARDS implants are made from Titanium alloy. The ARDS implants geometrical shape is characterized by altering drilling profile, with double thread at the upper part that change to one thread at the lower part, which increases its surface, and as a result, increases in the preliminary contact surface with the bone. The ARDS dental implants are : **S type:** Internal hex implants, length 10/13 mm, diameter 3.75/4.5 mm, with double thread at the upper part that goes over in a single thread at the lower part. S implant types are supplied sterile in a double vial system, inside a plastic box which includes the covering screw and the Instructions For Use. The abutments are for single use only and supplied non-sterile. The tools are reusable and supplied non-sterile, they must be sterilized by autoclave before use.
5.	***Intended Use:***	ARDS dental implants are indicated for use in surgical and restorative applications for placement in the bone of the upper and lower jaw to provide support for prosthetic devices in order to restore the patient's chewing function. ARDS dental implants are indicated for two-stage surgery.
6.	***Comparison of Technological Characteristics:***	With respect to technology and intended use, the ARDS dental implants are substantially equivalent to its predicate device which is the Alpha Bio Dental Implant System. The primary differences are propriety in nature. Based upon its testing results, ARDS believes these differences do not raise additional safety of efficacy concerns.

Revised March 9, 2008